

### **REMARKS**

Claims 1-83 are pending in the current application. Applicants provisionally elected claims 1-16, 22-24, 32-33, 36-38, 43, 80, 82 and 83 in response to the Restriction Requirement issued by the Examiner on October 2, 2002 (Paper No. 6). In the Office Action issued on June 26, 2003 (Paper No. 9), the Examiner further withdrew claims 22-24, 80, 82 and 83 as being drawn to a non-elected invention. In response to Paper No. 9, Applicants submitted an Amendment on October 27, 2003, amending claims 1-4, 7, 12, 13 and 15. In the Office Action issued on July 23, 2004, the Examiner objected to claims 36-38 as depending from non-elected claims 22-24, and rejected claims 1-12, 14-16, 32, 33 and 43. By way of the present Amendment, Applicants have amended claims 1 and 12, and canceled claims 36-38. Claims 1-16, 32, 33 and 43 are therefore currently under examination.

#### **Withdrawal of Finality of the Office Action**

Applicants respectfully acknowledge the Examiner's withdrawal of the finality of the previous Office Action. Applicants herein provide a brief summary of the communication history among Applicant's representatives, Dr. Kathryn Doyle and Dr. Thomas Sossong, Examiner Saoud, and the Examiner's supervisor, Examiner Gary Kunz, leading to the Examiner's present withdrawal of the finality of the previous Office Action.

On June 14, 2004, Dr. Kathryn Doyle left a voicemail for Examiner Saoud, requesting that the finality of the May 5, 2004, Office Action be withdrawn, as the rejection levied against claims 12 and 33 in that Office Action had not previously been set forth by the Examiner, making the rejection a new rejection based in no part on Applicant's Amendment or response.

On June 15, 2004, Examiner Saoud left a voicemail with Dr. Doyle stating that the Examiner's prior failure to set forth the rejection of claims 12 and 33 was merely a "typographical error," thereby refusing to withdraw the finality of the Office Action issued on May 5, 2004.

In a telephone conference on June 16, 2004, Applicants' representatives,

Drs. Kathryn Doyle and Thomas Sossong, discussed with the Examiner's supervisor, Examiner Gary Kunz, the Final Office Action issued on May 5, 2004. In that conference, Examiner Kunz determined that the finality of the May 5, 2004, Office Action would be withdrawn, because in that Office Action, Examiner Saoud had identified a new grounds of rejection that was not based on Applicants' arguments or amendments.

Applicants are filing concurrently herewith a Petition Under 37 C.F.R. § 1.59(B) To Expunge Information Or Copy Of Papers In Application concomitantly herewith to expunge the present Interview Summary from the application file as containing an inaccurate account of the discussion between Drs. Kathryn Doyle and Thomas Sossong, and Examiner's Saoud and Kunz. Language is proposed in the Petition that reflects an accurate account of the discussions.

#### Claim Notation

In the Office Action, the Examiner indicated that claim 31 was improperly notated as being an "original" claim. Applicants have herein amended the notation of claim 31 to properly reflect that the claim is "withdrawn."

#### Objections to the Claims

The Examiner has objected to claims 36-38 as depending from non-elected claims 22-24. Applicants have canceled claims 36-38 herein, and accordingly, Applicants respectfully submit that the Examiner's objection has been overcome.

#### Rejections under 35 U.S.C. § 112, second paragraph

The Examiner has set forth several rejections under 35 U.S.C. § 112, second paragraph. First, it is the Examiner's view that claim 1 is indefinite because it is not clear if the nucleic acid or the FGF-23 of the claim "comprises SEQ ID NO:1." Applicants have amended claim 1 to recite "An isolated nucleic acid comprising SEQ ID NO:1..." Accordingly, Applicants respectfully submit that claim 1 distinctly claims the subject matter of the invention, and therefore, the Examiner's rejection has been overcome.

Secondly, the Examiner has rejected claims 1-4 and 43, and dependent

claims 5-11 and 32, as being indefinite for recitation of the phrase “biological activity of FGF23.” Applicants respectfully disagree and submit that the phrase “biological activity of FGF23” is not indefinite for the following reasons.

In the specification, at lines 27-32 on page 20, Applicants specifically describe the “biological activity of FGF23” as the “ability of a molecule to bind an FGF receptor and alter phosphate transport,” either in vivo or in vitro. Further, on page 24 of the instant application, from line 18 through line 29, Applicants describe both wild type and mutant FGF23 molecules, and describe that mutant FGF23 molecules of the invention have enhanced properties including those such as protein stability, resistance to proteolytic degradation, increased half-life, among others. Such enhanced properties of FGF23 polypeptides of the invention relate to the same basic property of FGF23, namely, the “ability of a molecule to bind an FGF receptor and alter phosphate transport,” either in vivo or in vitro. That is, wild type and mutant FGF23 molecules of the present invention do not have “different” activities as defined by the Examiner, but rather, have different levels or degrees of the same activity, as defined in the as-filed specification. This is in contrast to the Examiner’s assertion that the FGF23 molecules of the present invention have “different” activities.

For example, an FGF23 mutant of the present invention having greater resistance to proteolytic degradation than wild type FGF23 would be able to exert the same biological activity, i.e., the “ability of a molecule to bind an FGF receptor and alter phosphate transport,” for a longer period of time than would wild type FGF23. Therefore, Applicants respectfully submit that claims 1-4 and 43, and dependent claims 5-11 and 32, are not indefinite, and that the claims are imbued with sufficient antecedent basis.

Accordingly, Applicants respectfully submit that claims 1-4 and 43, and dependent claims 5-11 and 32, do indeed distinctly claim the subject matter of the invention, and therefore, the Examiner’s rejections of the claims is improper and should be withdrawn.

The Examiner has also rejected claim 12, and dependent claims 14-16 and 33, as being indefinite for recitation of the phrase “fibroblast growth factor-23 (FGF23),” because in the Examiner’s view, the metes and bounds of what the term encompasses are

not clear. Applicants have amended claim 12 to recite a “nucleic acid comprising SEQ ID NO:1.” Applicants respectfully submit that, in view of the amendment to claim 12, the Examiner’s rejection of claim 12 and of dependent claims 14-16 and 33 has been overcome, and Applicants therefore request withdrawal of the rejection.

Rejection under 35 U.S.C. § 102(e)

Claims 3, 4, 12 and 33 were rejected under 35 U.S.C. § 102(e) as being anticipated by either Itoh et al. (2002, U.S. Patent Application Publication No. 2002/0082205 A1) or Milne Edwards et al. (2002, U.S. Patent Application Publication No. 2002/0102604 A1).

It is the Examiner’s view that Itoh et al. discloses a protein which is 100% identical to “the protein of the instant application,” as well as a nucleic acid encoding such a polypeptide, and that the effective filing date of Itoh et al. is March 8, 2000, which is prior to the July 19, 2000, effective filing date of the instant application. It is also the Examiner’s view that Milne Edwards et al. teaches a nucleic acid molecule that encodes a protein that is 100% identical to “the protein of the instant application,” as well as a nucleic acid encoding such a polypeptide, and that the effective filing date of Milne-Edwards et al. is December 8, 1999, which is prior to the July 19, 2000, effective filing date of the instant application. Applicants respectfully overcome the Examiner’s rejections as set forth more fully below.

Applicants respectfully submit that, in making the rejections under 35 U.S.C. § 102(e), the Examiner has mischaracterized the present claimed invention. Specifically, the Examiner alleges that Itoh and Milne-Edwards both disclose a polypeptide identical to “the” protein of the instant application. Applicants respectfully point out that the presently claimed invention properly claims more than “one” protein. For example, Applicants direct the Examiner’s attention to claim 2, which includes a polypeptide having an amino acid sequence that shares at least 98% sequence identity with the amino acid sequence of SEQ ID NO:2. Therefore, Applicants respectfully submit that the Examiner’s rejections under 35 U.S.C. § 102(e) are properly directed to only one polypeptide of the presently-claimed invention, namely, the polypeptide set forth in SEQ ID NO:2.

A rejection under 35 U.S.C. § 102(e) requires, in relevant part, that the “invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent.” (emphasis added). Applicants respectfully submit that the Itoh and Milne-Edwards references do not satisfy this requirement.

Applicants provide herewith a Declaration of inventors Michael J. Econs, Kenneth White, Tim Matthias Strom, and Thomas Meitinger, submitted in accordance with 37 C.F.R. § 1.131. The inventors’ Declaration sets forth and asserts that the isolation of an FGF23 nucleic acid (SEQ ID NO:1) encoding the amino acid sequence set forth in SEQ ID NO:2 of the present patent application was conducted in the United States on a date before December 8, 1999. Evidence of Applicants’ conception of the present invention is presented in Exhibit A, submitted herewith, which is an invention disclosure made by Applicants prior to December 8, 1999. In part, Exhibit A evidences the identification, isolation, and sequence determination of the nucleic acid of SEQ ID NO:1 and the amino acid sequence of SEQ ID NO:2, and identifies the sequences, as set forth in detail in the as-filed application. Accordingly, the subject matter of pending claims 3, 4, 12 and 33 was invented by Applicants prior to the earliest priority dates of December 8, 1999, and March 8, 2000, of the cited references of Milne-Edwards et al. (U.S. Patent Application Publication No. US 2002/0102604 A1) and Itoh et al. (U.S. Patent Application Publication No. US 2002/0082205 A1), respectively.

Thus, the cited references of Milne-Edwards and Itoh are not 35 U.S.C. § 102(e) prior art to present claims 3, 4 12 and 33. Accordingly, Applicants respectfully submit that the Examiner’s rejection under 35 U.S.C. § 102(e) has been overcome and respectfully request that the rejection be reconsidered and withdrawn.

#### Allowable Subject Matter

Applicants acknowledge the Examiner’s determination that claim 13 would be allowable “if rewritten in independent form including all of the limitations of the base claim and any intervening claims.” The Examiner’s determination appears to be based on the dependence of claim 13 on claim 12, which claim was rejected by the Examiner as set forth in detail above.

Applicants respectfully submit that, because claim 12, amended as described herein, is in full condition for allowance, claim 13 is also in full condition for allowance and need not be amended. Accordingly, Applicants have not amended claim 13 herein.

Summary

The amendments made herein are supported in the as-filed specification, and as such, no new matter has been added by way of the present amendment. Applicants respectfully submit that each and every rejection or objection set forth by the Examiner has either been overcome or is now inapplicable, and that the instant application is in full condition for allowance. Favorable examination of the claims on the merits is respectfully requested.

Respectfully submitted,

**MICHAEL ECONS *ET AL.***

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(Date)

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Enclosures: Petition to Expunge; Petition for Extension of Time; Exhibit A